

the treatment of histamine induced disturbances (see Abstract, Column 1) and allergies (Column 6, line 72), it is not seen where the above cited passage adds anything to the disclosure of the Vogelsang patent. The Examiner has referred on page 3 of the Office Action to the use of "preseruahres" (sic) in this connection, but this comment is not understood. Therefore, it is the disclosure of the Vogelsang patent which is the focus of the following remarks.

In his discussion of this patent, on page 3 of the Office Action, the Examiner has referred to column 43 lines 5-15 of Vogelsang, but this comment also is not understood. There is no column 43 in this patent.

The only information in the Vogelsang patent on mode of administration is in the paragraph bridging columns 6 and 7, viz.

The compounds according to the present invention are used as active ingredients in pharmaceutical preparations and may be administered in usual embodiments such as tablets, dragees, capsules, suppositories, drops, ointments, creams as well as injection solutions. They are in particular used for the treatment of the various forms of allergies. Thus, they have been used successfully in humans in the treatment of asthma bronchiale, for the treatment of various disorders of the skin and mucous membranes hay fever and rhinitis vas-motorica. In general, they are administered in such treatments in a dosage of 0.4 to 4 mg. per day and human patient. The symptoms of the above allergic diseases may be effectively reduced upon a single dose for up to 24 hours. The effectiveness of the components of the present invention in humans which is produced very rapidly and over a prolonged period of time in comparison to other antihistamines, may be particularly well shown in the reduction of the size of an artificially produced lesion by means of a histamine liberator according to L. Kerp, H. Kasimiar, P.N. Tie, Med. Welt 17 NF 2794 (1966). The

compounds according to the present invention may be used as such or in combination with other active ingredients as they are usual in antihistaminic preparations.

The portion which has been underlined appears to be the sole basis for the rejection, and more particularly the disclosure that the compounds "may be administered in...drops..." To this, the Examiner has added the following comment:

It would have been obvious to administer the azelastine composition of Vogelsang directly to the nasal tissues or conjunctival sac...because these are the areas to which medicament drops are normally applied."

However, the Examiner has indulged in a leap of logic which is not supported by the reference in making this comment. The reference does not say that drops are administered to the patient. It merely says that the compounds may be administered in drops. Thus, a medicine dropper is a well known device for measuring liquids. See for example page 1329 in the attached extract from *The United States Pharmacopoeia* which describes the use of a medicine dropper and its ability to deliver a measured quantity of liquid, with various degrees of precision. But there is no indication of where the drops are to be delivered. For example, a medicine dropper is used as a means of delivering a measured quantity of a concentrated liquid to water which is to be swallowed or used as a mouthwash.

The Examiner has cited no reference to support his contention that "the nasal tissues or conjunctival sac...are the areas to which medicament drops are normally applied." However, such a sweeping statement, which provides the sole link between the Vogelsang patent and the present invention, should be supported by a reference.

Referring again to the attached extract from *The United States Pharmacopoeia*, it will be noted that various modes of administration are discussed. Compositions which are intended to be administered to the nose are referred to as "Nasal Solutions" and compounds which are administered to the eye are referred to as "Ophthalmic Solutions", see pages 1655 and 1338. On the other form, among the forms of medicine which are described, the word "drops" does not appear as a form of material to be administered to the eyes or nasal passages.

Similarly, the words "ointment" and "cremes" are used in the reference, and these are mentioned in the attached copy of an extract from Remington's *Pharmaceutical Sciences*. See pages 1594 and 1616. However, there is no indication of direct application to nasal passages and eyes.

Finally, there is attached a copy of an extract from *Drug Facts and Comparisons*. While numerous antihistamines are mentioned, and modes of administration are described, there is no suggestion of direct application to the eyes and nasal passages. Dosage forms such as capsules, tablets, injections, suppositories, elixirs and syrups are described, but none for direct application to the eyes and nasal passages.

Therefore, the only link between the present invention and the cited Vogelsang reference is the Examiner's interpretation of the word "drops" in this patent, and the Examiner's unsubstantiated comment that "the nasal tissues or conjunctival sac...are the areas to which medicament drops are normally applied." However, as indicated above, such a sweeping statement, providing the sole link between the reference and the present invention and the cited patent,

Helmut HETTCHE  
Serial No. 07/551,664  
Page 5

ought to be supported by a reference. Since none has been cited, it is submitted that the claims should be allowed.

Further, applicant submits that the Examiner should consider the decision in the case of *Ex parte Keith*, 154 USPQ 320, which held:

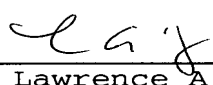
Asserted inherency must be a necessary result and not merely a possible result.  
*Ex parte Vander Wal et al.*, 705 O.G. 5,  
1956 USPQ 11, 109 USPQ 119, and decisions cited therein.

Here, the Examiner reasons that the only possible meaning of the reference to "drops" in the reference is that they are to be applied directly to the eyes and nasal passages. However, the Examiner has not shown, by citation of a reference, or in any other way, that this is the only possible meaning of the word "drops." Rather, a medicine dropper is simply a device for measuring a liquid. While droppers are used to administer liquid medications to eyes and nasal passages, this does not mean that this mode of administration is the "necessary" and only "possible" inference to be drawn from the reference to "drops" in the cited patent.

For these reasons, it is submitted that the claims are patentable and that they should be allowed.

Respectfully submitted,  
CUSHMAN, DARBY & CUSHMAN

By

  
Lawrence A. Hymo  
Reg. No. 19,057

1615 L Street N.W.  
Washington, D.C. 20036

Telephone (202) 861-3000